UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/403,085	01/07/00	ELAISSARI A	104560

HM12/0314

OLIFF & BERRIDGE
PO BOX 19928
ALEXANDRIA VA 22320

EXAMINER	
GABEL, G	

ART UNIT	PAPER NUMBER
1641	6

DATE MAILED: 03/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/403,085	ELAISSARI ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *07 January 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☒ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☒ Notice of References Cited (PTO-892)
15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

Drawings

1. This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings in this application are also objected to by the Draftsperson (see PTO-948 attached). Correction is required. However, formal correction of noted defect can be deferred until application is allowed by the examiner.

Specification

2. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.

1. Field of the Invention.
2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

Information Disclosure Statement

3. The Information Disclosure Statement (PTO-1449) filed 1/7/00 is acknowledged. Reference 2 268 818 was not considered because neither an English translation nor a statement of relevancy was provided therefor.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 has unclear and improper antecedent basis problems in reciting "Process for isolating a target biological material". Change to --A process for isolating a target biological material-- for clear and proper antecedent basis.

Claim 1 fails to recite active and positive method steps in reciting "said target biological material being placed in contact with at least the capture phase". Specifically claim 1 fails to distinctly define the process involved in the instant invention; thereby, rendering the claim indefinite. Language such as "contacting ..., capturing ..., detecting ..." is suggested to obviate this rejection.

Claim 1 is indefinite in reciting "said process being characterized in that" because it is unclear what is encompassed by the term "characterized" in relation to the requirements or limitations following the claim. Language such as "consisting of" or "comprising" is suggested to assist in obviating this rejection. See also claims 2-24.

Claim 1 is vague and indefinite in reciting "linear form" and "linear polymer" because it is unclear what is encompassed by the term "linear" as recited in the claim. See also claims 3, 14, 23, and 24.

Claim 1 is vague and indefinite in reciting "apparent nature" because the term "apparent" is a subjective term that lacks a comparative basis for defining its metes and bounds. See also claims 3, 23, and 24.

Claim 1 is confusing in reciting "complex is detected" in line 7 and "complexing groups" in line 12 because similar terms appear to be used interchangeably to refer to different structures. Alternatively, it is unclear what structural cooperative relationship exists between the "complex" in line 7 and "complexing groups" in line 12. See also claims 3, 16, 23, and 24.

Claim 1 is ambiguous in reciting "linked by coordination to a first transition metal" because it is unclear what is encompassed by the term "coordination". Does Applicant intend "binding" or "conjugating". See also claims 3, 23, and 24.

Claim 1 fails to recite a positive active method step in reciting "capable of specifically recognizing". Further, it is unclear what is encompassed by the term "recognizing". Does Applicant intend the term "recognition" as encompassing "specificity" or "affinity". See also claims 3, 23, and 24.

Claims 2-22 have unclear and improper antecedent basis problems in reciting "Process according to claim". Change to --The process according to claim -- for clear and proper antecedent basis.

Claim 2 is unclear in reciting "capture phase comprises a marker in order to obtain a detection phase" because it is unclear what is intended by the phase "in order to obtain" as recited in the claim. Does Applicant intend "for use as detection phase."

Claim 3 has improper antecedent support in reciting "a detection phase". Alternatively, it is unclear what structural and functional cooperative relationship exists between the "a detection phase" in claim 3 and the "marker/detection phase" in claim 2.

Regarding claim 4, "and/or" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See also claims 5, 9, 16, 17, 18, 19, and 25.

Regarding claim 5, the term "derivative" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "derivatives"),

thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d). See also claim 8.

Claim 5 has unclear and improper antecedent support in reciting "of acrylamide" and "of methacrylamide". Change to "of an acrylamide" and "of a methacrylamide" for clear and proper antecedent basis.

Claim 6 recites improper Markush language in reciting "the water soluble monomer is chosen from". Change to "the water soluble monomer is selected from the group consisting of" for proper Markush language.

In claim 6, it is unclear what structural cooperative relationship exists between "the water soluble monomer" in line 4 and the "first monomer" in line 9. Please clarify.

Claim 8 recites improper Markush language in reciting "the functional monomer is chosen from". Change to "the functional monomer is selected from the group consisting of" for proper Markush language.

Claim 12 recites improper Markush language in reciting "said core is chosen from". Change to "said core is selected from the group consisting of" for proper Markush language.

Claim 17 recites improper Markush language in reciting "transition metal is chosen from". Change to "transition metal is selected from the group consisting of" for proper Markush language.

Claim 21 recites improper Markush language in reciting "the marker for the detection phase is chosen from". Change to "the marker for the detection phase is selected from the group consisting of" for proper Markush language.

Claim 21 recites improper Markush groups in reciting "an enzyme, biotin, ..., fluorescent component, radioactive component, ... an antigen, a hapten" because the claim includes both "label components" or "binding components". Please clarify.

Claim 21 is vague and indefinite in relation to claims 2 or 3 to which it depends from because it is unclear what structural and functional cooperative relationship exists between the marker/detection phase in the instant claim and "detection phase" in claim 3 and the "marker/detection phase" in claim 2.

Claim 22 recites an acronym in reciting "ELISA". Acronyms and abbreviations must be fully defined at least one time in a given set of claims.

Claim 23 has unclear and improper antecedent basis problems in reciting "Phase for capturing a target biological material". Change to --A phase for capturing a target biological material -- for clear and proper antecedent basis.

Claim 24 has unclear and improper antecedent basis problems in reciting "Phase for detecting a target biological material". Change to --A phase for detecting a target biological material -- for clear and proper antecedent basis.

Claim 25 has unclear and improper antecedent basis problems in reciting "Reagent for isolating a target biological material". Change to --A reagent for isolating a target biological material -- for clear and proper antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1-8, 10-12, 14-15, and 17-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nowinski et al. (US 4,843,010).

Nowinski et al. disclose a process of isolating (separating) a target biological material (analyte) in a sample by contacting the target with a capture phase to form a complex. The capture phase comprises a monomer-biological species conjugate (monomer-reactant conjugate) wherein the biological species is an antigen or antibody that specifically recognizes the target. Specifically, the biological species is covalently linked with a functionalized polymer obtained by polymerization of a water-soluble monomer such as acrylamide or methacrylamide (see column 2, lines 40-62 and column 1, lines 50-59). The monomer is typically an ethylenically or acetylenically unsaturated compound containing a functionality for coupling to the biological species; such functionalities include covalently bondable functionalities such as carboxyl, amine, etc. (see column 6, lines 55-67). The monomer, biological species, and its specific target bind through interaction to form a complex by initiating polymerization reaction;

thereby rapidly and conveniently separating the complex or isolating the target from the solution (see column 3, lines 40-53). The isolation of bound from free biological species is effected by polymerization reaction (see column 4, lines 45-47). Nowinski teach that the biological species includes a marker or detection phase (reporter) which is capable of producing a detectable signal, either alone or in combination with the capture phase, such as radioisotopes, fluorophores, chromophores, and luminescent compounds (see column 5, lines 3-8). In addition, the complexing groups may further be linked to or include photoinitiators for photoinitiated polymerization using transition metals such as iron or cobalt (see column 9, lines 58-65). The solid phase supports taught by Nowinski et al. (insoluble polymer particles) comprise cores which are cross-linked for immobilization of biological species; these include polystyrene and polyacrylamides (see column 2, lines 15-19). In column 5, Nowinski et al. disclose that the isolation or separation procedure encompass agglutination reactions and ELISA techniques. The pH range used in the process varies widely from pH 3 to pH 10 although it is preferable to select a pH wherein the biological species remains stable, i.e. above or equal to the isoelectric point of the species (see column 9, lines 21-37). According to Nowinski et al., by varying the chemical composition or ratios of monomers, it is possible to form either hydrophilic (soluble) or hydrophobic (insoluble) polymers which comprise a broad range of chemical and physical structures including linear, branched, or cross-linked structures (see column 2).

6. Claims 1-5, 8-15, 17, and 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Rohr et al. (US 5,445,971).

Rohr et al. disclose a method of isolating (partitioning) a target biological material (analyte such as nucleic acid, protein, peptide) contained in a sample using a particle composition comprising a capture phase and a detection phase (solid phase reagent and magnetically-labeled reagent) (see column 3, lines 19-39). Rohr et al. disclose that the capture phase has a core comprising polystyrene or polyacrylate material with a transition metal layer (magnetic layer) and a non-magnetic coating which comprises a polymer having functional groups for binding a target (see Table 1). The capture phase also includes a matrix comprising acrylamide and methacrylamide and is selected to include reactive functional groups such as carboxylic groups for facilitating the attachment of the target with the biological species (binding members). The particulate size is preferably between 0.01 μm to 10 μm (see columns 12 and 13). Alternatively, the solid phase material can also take the form of tubes or slides or wells in a plate (see column 14, lines 3-5). The particle also has a detection phase which includes a biological species that is linked into the transition metal to an extent which permits isolation and detection of bound target biological material from unbound material (see column 6, lines 35-62 and column 13, lines 16-22). The transition metals include iron, nickel, cobalt, manganese, etc. (see column 10, lines 11-15).

7. Claims 1-5, 9, 10-12, 15, 17, 19-21, and 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Owen et al. (US 5,866,099).

Owen et al. disclose magnetic polymer particles which are magnetic due to inclusion of magnetic metal compounds such as iron and magnetite into polyacrylamine or polyacrylic polymers. The polymer particles have a size that is about 0.01 – 0.2 microns (see columns 3 and 4). The polymer particles can be tailored to include monomers which exhibit a specific biofunctional activity such as antibodies (Example 2) and a marker (radioisotope) for use as a tracer of protein component (Example 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rohr et al. (US 5,445,971) or Owen et al. (US 5,866,099) in view of Schaeffer et al. (US 4,784,912).

Rohr et al. and Owen et al. have been discussed supra. Rohr et al. and Owen et al. fail to disclose N-isopropylacrylamide as the water-soluble monomer incorporated into the capture phase or polymer particles.

Schaeffer et al. disclose polymeric latex particles which have incorporated thereto recurring units of hydrophilic or water soluble polymerizable monomers including acrylamide, methacrylamide, and N-isopropylacrylamide (see column 5).

One of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in substituting N-isopropylacrylamide such as taught by Schaeffer for the acrylamide or methacrylamide on the solid phase particle taught by Rohr or otherwise incorporate N-isopropylacrylamide such as taught by Schaeffer into the magnetic particles taught by Owen because Rohr specifically required use of hydrophilic polymerizable monomers and Owen specifically suggested incorporation of such functional monomers into his magnetic particles and Schaeffer specifically taught that N-isopropylacrylamide, like acrylamide and methacrylamide, belongs to the same category of hydrophilic or water-soluble polymerizable monomers.

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nowinski et al. (US 4,843,010) or Rohr et al. (US 5,445,971) in view of Ohdaira et al. (US 5,132,243).

Nowinski et al. and Rohr et al. have been discussed supra. Nowinski et al. and Rohr et al. fail to teach that the functional monomers include complexing groups derived specifically from itaconic acid or maleic anhydride-co-methyl vinyl ether.

Ohdaira et al. disclose polymeric latex particles which have incorporated thereto a copolymer of ethylene and an α,β-ethylenically unsaturated carboxylic acid and further having an aromatic vinyl compound grafted thereto. The α,β-ethylenically unsaturated carboxylic acid is at least one of itaconic acid and maleic acid (see column 2). Further, the polymer particle can be sensitized or chemically bonded with an immuno-serologically active material such as antigen or antibody (see column 4).

One of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in substituting itaconic acid or maleic acid such as taught by Ohdaira for the carboxylic acid in the polymer particles taught by Nowinski or Rohr because both Nowinski and Rohr use generic types of carboxylic groups to facilitate attachment of biological species into the polymer particles and Ohdaira specifically taught using itaconic acid and maleic acid for the same general purpose.

Remarks

10. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Adamczyk et al. (US 5,459,080) disclose ion-capture assays using a specific binding member conjugated to carboxymethylamylose.

J. Porath (Metal chelate affinity chromatography, 1975) teaches that proteins have specific affinity for heavy metal ions which provides a basis for their purification and analysis. Specifically, histidine and cysteine are known to form stable complexes with zinc and copper ions.

Smith et al. (US 6,027,945) disclose a method of isolating biological target materials using silica magnetic particles.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday, 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
March 8, 2001

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

03/09/01